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| EXAMINER | | | | |
| SIEFKE, SAMUEL P | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/828,624

Applicant(s)

SCHOMACKER ET AL.

Examiner

SAM P. SIEFKE

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-19 and 42-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-19 and 42-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

Claims 16-19 and 42-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Biel (USPN 6,083,487) in view of Richards-Kortum et al. (USPN 6,187,289).

Biel discloses a methylene blue and toluidene blue mediated fluorescence diagnosis of cancer which comprises; applying a contrast agent (methylene blue or toluidene, col. 2, line 34-col. 3, line 10) to a region of a tissue sample (cancer; col. 1, line 24); obtaining an optical signal (fluorescence, col. 2, line 34) from the region within a predetermined period of time (col. 2, lines 23-24; up to 10 minutes is predetermined) that is optimal for observing a characteristic of the tissue (cancer; col. 1, line 24) in a peak whitening period of reflectance or peak darkening of fluorescence of tissue (col. 2, lines 53-62); and identifying the characteristic of the region based at least in part on the optical signal (claim 1). Since Biel allows for tissue activation to occur up to 10 minutes to pass before performing a fluorescence measurement the Examiner states this would be the optimal peak darkening of fluorescence of the tissue which allows for optimal detection. Performing a linear discriminant analysis of the reference set of data (this is just a linear or non-linear plot of the normal tissue against the cancerous tissue as seen in figs. 1-4). Biel teaches that after application of the photosensitizer (contrast agent), it is selectively retained by diseased tissue so that after a period of time, determined by

the kinetics of the compound's distribution, there is more photosensitizer in the diseased tissue than in the normal tissue. The photosensitizer is then activated with a specific wavelength of light matching the absorption characteristics of the specific photosensitizer, typically using a laser." This clearly indicates that a period of time is determined for optimal time for the contrast agent (depending on the type of photosensitizer used) to be absorbed into the tissue sample for further detection. Different contrasting agents have different periods of time at which detection is optimal for detecting characteristics in a tissue.

Biel does not teach the use of a reflectance signal as one of the optical signals used to observe a characteristic in the tissue; a specific time window after application of the contrast agent that is optimal to observe a characteristic in a sample.

Richards-Kortum discloses a method of using an acetic acid as a contrast in reflectance confocal imaging of tissue that comprises; applying a contrast agent (acetic acid, col. 3, lines 14-19) to a region of a tissue sample (breast cancer, cervical cancer, epithelium, cancer; col. 1, line 18; col. 2, line 38); obtaining an optical signal (reflectance, col. 1, line 15, claim 1) from the region within a predetermined period of time (claim 15, predetermined period is immediate because it is in real-time) that is optimal for observing a characteristic of the tissue (breast cancer, cervical cancer, epithelium, cancer; col. 1, line 18; col. 2, line 38); and identifying the characteristic of the region based at least in part on the optical signal (claim 1, 6,8,15). It would have been obvious to one having an ordinary skill in the art to modify Biel to include using reflectance imaging of Richards because it is well know in the art of optical reactions to

use a reflectance imaging to view a sample that has been applied with a contrasting agent. Regarding claims that involve taking multiple reflectance images, the prior art teach the use of real-time imaging in which multiple images are produced as time progresses. Regarding the specific time windows for optimal observation of a sample, it would have been obvious to one of ordinary skill in the art to follow routine experimentation to create a time window for specific contrasting agents that renders an optimal time period for observing a characteristic of a tissue because each contrast agent has different kinetics for the compound distribution throughout the sample.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-19 and 42-57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,933,154. The instant invention does not explicitly recite the claim limitations of acetic acid for the contrasting agent, as claimed by Patent No. 6,933,154. However, the presently pending claims 16-19 and 42-58 are a broader version of Patent No. 6,933,154. 6,933,154 claims include all the limitations found in the presently pending claims. Thus, the presently pending claims cover all the subject matter of 6,933,154.

Response to Arguments

Applicant's arguments filed 9/17/08 have been fully considered but they are not persuasive. Applicant argues, "Biel only discloses a period of up to ten minutes after application of the contrast agent before obtaining spectral data, but is also silent as to optimizing the data collection time by concentrating on the window of time having peak whitening or darkening. (See Biel at Col. 2, lines 23-28)." Examiner pulls a statement from the instant application, "In one embodiment, the peak whitening window lies between about 30 s and about 130 s; and in another embodiment from about 20 s to about 180 s. For fluorescence, the peak "darkening" window lies between about 50 s and about 150 s with a minimum at about 80 s. Since Biel allows for tissue activation to occur up to 10 minutes to pass before performing a fluorescence measurement the Examiner states this would be the optimal peak darkening of fluorescence of the tissue which allows for optimal detection. Any time beyond 10 minutes would not be in the optimal peak window. Claim 1 only requires an optimal window of time but this

limitation is a relative term because it does not specifically set out an optimal time window as the specification states above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **SAM P. SIEFKE** whose telephone number is (571)272-1262. The examiner can normally be reached on **M-F 7:00am-5:00pm**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Jill A. Warden** can be reached on **571-272-1700**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel P Siefke/
Primary Examiner, Art Unit 1797